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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,311	07/19/2001	Heiner Max	Beiersdorf 733-KGB	9953

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	18

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/909,311	Applicant(s) MAX ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on June 12, 2003 in Paper No. 17 wherein claims 35-38 are newly submitted. Currently, claims 24-38 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-26 and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez et al. (5,296,472) for reasons of record stated in the Office Action dated March 12, 2003.

Applicant's remarks filed June 12, 2003 in Paper No. 17 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicant's arguments that "neither Sanchez not the Examiner provides evidences that cyclodextrins are known to reach the sebaceous glands and have the desired metabolic effects" and that "For this reason, Examiner's conclsory statements do not constitute a prima facie case of inherency" have been considered but not found

persuasive. First, the instant claims are not limited to reach the sebaceous glands and have the desired metabolic effects.

Secondly, most importantly, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known even though applicant has proposed or claimed the mechanism (e.g., reach the sebaceous glands and have the desired metabolic effects). Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps, i.e., applying to skin and/or hair. See *Ex parte Novitski*, 26 USPQ 2d 1389. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Therefore, Sanchez et al. anticipates Claims 24-26 and 28-29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 27 even though it is not anticipated by Sanchez et al. (5,296,472) as applicable to claims 24-26 and 28-29, is rejected under 35 U.S.C. 103(a) as being unpatentable over the same reference by Sanchez et al. (5,296,472) for reasons of record stated in the Office Action dated March 12, 2003.

Applicant's remarks filed on June 12, 2003 in Paper No. 17 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant argues that the Examiner may have misread claim 27. However, claim 27 reads on the claimed method comprising at least 30 wt. % of γ-cyclodextrin. Hence, one of ordinary skills in the art would clearly recognize that the 30 wt.% would be based on the composition's total weight.

As indicated in the previous Office Action, Sanchez et al. does not expressly disclose the composition therein comprising at least 30% weight of γ–cyclodextrin. However, the previous Office Action also discusses that Sanchez et al. discloses that the effective amounts of cyclodextrin component broadly including α-,β-, γ-cyclodextrins in the topical compositions therein are about 1-30% by weight and most prefereably 10% by weight, within the instant claims. See col.2 lines 57-63 in particular. Therefore, one of ordinary skill in the art would have found it obvious to employ at least 30% weight of the particular known cyclodextrin, γ–cyclodextrin, in Sanchez's compositions because the optimization of known effective amounts of known active agents to be administered

according the disclosures of Sanchez et al., is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Claims 30-34, and newly submitted claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez et al. (5,296,472) essentially for reasons of record stated in the Office Action dated March 12, 2003.

Sanchez et al. discloses methods for delipidation of skin and/or hair or for controlling the excessive buildup of sebum on mammalian skin or hair comprising topically applying to skin and/or hair an effective amount of a composition comprising a cyclodextrin component having one or more cyclodextrin. See abstract, col.1 lines 14-17 and 31-33, col.3 lines 13-14 and 61-65, and col.8-9 Example 3-5, in particular. Sanchez et al. also discloses that the effective amounts of cyclodextrin component broadly including α-,β-, γ-cyclodextrins in the topical composition therein are about 1-30% by weight and most prefereably 10% by weight. See col.2 lines 57-63 in particular. Sanchez et al. further discloses that the cyclodextrin compositions therein may be creams, gels, solutions suspensions; the cyclodextrin compositions therein may further comprise non-polar solvents, waxes and other type of lipid-type agents, in 10% by weight (see col.5 lines 12-20 and 64-66 in particular); these oily components are known used for skin treatment (see col.5 lines 12-20 in particular). It is noted that non-polar

solvents, waxes and other type of lipid-type agents are known to be an oil phase and also clearly read on the instant oily components recited in claim 38 herein.

Sanchez et al. does not expressly disclose that a particular composition comprising an oil phase and a cyclodextrin component having one or more cyclodextrin employed in the claimed method herein. Sanchez et al. also does not expressly disclose this particular composition comprising at least 30% weight of γ–cyclodextrin.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a particular composition comprising an oil phase and a cyclodextrin component having one or more cyclodextrin in the claimed method herein and to employ this particular composition comprising at least 30% weight of γ–cyclodextrin.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a particular composition comprising an oil phase and a cyclodextrin component having one or more cyclodextrin in the claimed method herein because it is known that the compositions of Sanchez et al. comprising a cyclodextrin component having one or more cyclodextrin for skin and hair treatments therein may further comprise oils, waxes and other known lipid-type agents, which reads on an oil phase and instant oily components recited in claims herein.

Therefore, one of ordinary skill in the art would have found it obvious to further employ an oil phase such as oils, waxes and other known lipid-type agents in a particular composition of Sanchez et al.

As discussed above, one having ordinary skill in the art at the time the invention was made would have been motivated to employ this particular composition comprising at least 30% weight of γ–cyclodextrin since the effective amounts of cyclodextrins broadly including α-,β-, γ-yclodextrins in the topical compositions therein employing in the methods therein are known to be about 1-30% by weight according to Sanchez et al.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on June 12, 2003 in Paper No. 17 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

The specification contains no clear and convincing evidence of nonobviousness or unexpected results for the claimed method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
August 14, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

8/24/03